Message

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Sent: 6/17/2019 3:13:41 PM
To: Anderson, Steve [Anderson.Steve@epa.gov]; Askinazi, Valerie [Askinazi.Valerie@epa.gov]; Baptist, Erik [Baptist.Erik@epa.gov]; Barkas, Jessica [barkas.jessica@epa.gov]; Beck, Nancy [Beck.Nancy@epa.gov]; Bertrand, Charlotte [Bertrand.Charlotte@epa.gov]; Blair, Susanna [Blair.Susanna@epa.gov]; Buster, Pamela [Buster.Pamela@epa.gov]; Canavan, Sheila [Canavan.Sheila@epa.gov]; Caraballo, Mario [Caraballo.Mario@epa.gov]; Carroll, Megan [Carroll.Megan@epa.gov]; Cherepy, Andrea [Cherepy.Andrea@epa.gov]; Christian, Myrta [Christian.Myrta@epa.gov]; Corado, Ana [Corado.Ana@epa.gov]; Davies, Clive [Davies.Clive@epa.gov]; Dekleva, Lynn [dekleva.lynn@epa.gov]; Devito, Steve [Devito.Steve@epa.gov]; Doa, Maria [Doa.Maria@epa.gov]; Drewes, Scott [Drewes.Scott@epa.gov]; Dunn, Alexandra [dunn.alexandra@epa.gov]; Dunton, Cheryl [Dunton.Cheryl@epa.gov]; Edelstein, Rebecca [Edelstein.Rebecca@epa.gov]; Edmonds, Marc [Edmonds.Marc@epa.gov]; Elwood, Holly [Elwood.Holly@epa.gov]; Fan, Shirley [Fan.Shirley@epa.gov]; Farquharson, Chenise [Farquharson.Chenise@epa.gov]; Fehrenbacher, Cathy [Fehrenbacher.Cathy@epa.gov]; Feustel, Ingrid [feustel.ingrid@epa.gov]; Frank, Donald [Frank.Donald@epa.gov]; Gibson, Hugh [Gibson.Hugh@epa.gov]; Gimlin, Peter [Gimlin.Peter@epa.gov]; Gorder, Chris [Gorder.Chris@epa.gov]; Gordon, Brittney [Gordon.Brittney@epa.gov]; Grant, Brian [Grant.Brian@epa.gov]; Gray, Shawna [Gray.Shawna@epa.gov]; Groeneveld, Thomas [Groeneveld.Thomas@epa.gov]; Guthrie, Christina [Guthrie.Christina@epa.gov]; Hanley, Mary [Hanley.Mary@epa.gov]; Helfgott, Daniel [Helfgott.Daniel@epa.gov]; Henry, Tala [Henry.Tala@epa.gov]; Kapust, Edna [Kapust.Edna@epa.gov]; Kemme, Sara [kemme.sara@epa.gov]; Koch, Erin [Koch.Erin@epa.gov]; Krasnic, Toni [krasnic.toni@epa.gov]; Lavoie, Emma [Lavoie.Emma@epa.gov]; Lee, Mari [Lee.Mari@epa.gov]; Lee, Virginia [Lee.Virginia@epa.gov]; Leopard, Matthew (OEI) [Leopard.Matthew@epa.gov]; Liva, Aakruti [Liva.Aakruti@epa.gov]; Lobar, Bryan [Lobar.Bryan@epa.gov]; Menasche, Claudia [Menasche.Claudia@epa.gov]; Morris, Jeff [Morris.Jeff@epa.gov]; Moss, Kenneth [Moss.Kenneth@epa.gov]; Mottley, Tanya [Mottley.Tanya@epa.gov]; Moyer, Adam [moyer.adam@epa.gov]; Myers, Irina [Myers.Irina@epa.gov]; Myrick, Pamela [Myrick.Pamela@epa.gov]; Nazef, Laura [Nazef.Laura@epa.gov]; Ortiz, Julia [Ortiz.Julia@epa.gov]; Owen, Elise [Owen.Elise@epa.gov]; Parsons, Doug [Parsons.Douglas@epa.gov]; Passe, Loraine [Passe.Loraine@epa.gov]; Pierce, Alison [Pierce.Alison@epa.gov]; Pratt, Johnk [Pratt.Johnk@epa.gov]; Price, Michelle [Price.Michelle@epa.gov]; Reese, Recie [Reese.Recie@epa.gov]; Reisman, Larry [Reisman.Larry@epa.gov]; Rice, Cody [Rice.Cody@epa.gov]; Richardson, Vickie [Richardson.Vickie@epa.gov]; Ross, Philip [Ross.Philip@epa.gov]; Sadowsky, Don [Sadowsky.Don@epa.gov]; Santacroce, Jeffrey [Santacroce.Jeffrey@epa.gov]; Saxton, Dion [Saxton.Dion@epa.gov]; Scarano, Louis [Scarano.Louis@epa.gov]; Scheifele, Hans [Scheifele.Hans@epa.gov]; Schmit, Ryan [schmit.ryan@epa.gov]; Schweer, Greg [Schweer.Greg@epa.gov]; Scott Selken [spselken@up.com]; Scott, Elizabeth [Scott.Elizabeth@epa.gov]; Selby-Mohamadu, Yvette [Selby-Mohamadu.Yvette@epa.gov]; Seltzer, Mark [Seltzer.Mark@epa.gov]; Sheehan, Eileen [Sheehan.Eileen@epa.gov]; Sherlock, Scott [Sherlock.Scott@epa.gov]; Simons, Andrew [Simons.Andrew@epa.gov]; Sirmons, Chandler [Sirmons.Chandler@epa.gov]; Slotnick, Sue [Slotnick.Sue@epa.gov]; Smith, David G. [Smith.DavidG@epa.gov]; Smith-Seam, Rhoda [smith-seam.rhoda@epa.gov]; Stedeford, Todd [Stedeford.Todd@epa.gov]; Stevens, Katherine [stevens.katherine@epa.gov]; Strauss, Linda [Strauss.Linda@epa.gov]; Symmes, Brian [Symmes.Brian@epa.gov]; Tanner, Barbara [Tanner.Barbara@epa.gov]; Thompson, Tony [Thompson.Tony@epa.gov]; Tierney, Meghan [Tierney.Meghan@epa.gov]; Tillman, Thomas [Tillman.Thomas@epa.gov]; Tomassoni, Guy [Tomassoni.Guy@epa.gov]; Tran, Chi [Tran.Chi@epa.gov]; Turk, David [Turk.David@epa.gov]; Vendinello, Lynn [Vendinello.Lynn@epa.gov]; Wallace, Ryan [Wallace.Ryan@epa.gov]; Wheeler, Cindy [Wheeler.Cindy@epa.gov]; Widawsky, David [Widawsky.David@epa.gov]; Williams, Aresia [Williams.Aresia@epa.gov]; Williams, Bridget [Williams.Bridget@epa.gov]; Williamson, Tracy [Williamson.Tracy@epa.gov]; Wills, Jennifer [Wills.Jennifer@epa.gov]; Wise, Louise [Wise.Louise@epa.gov]; Wolf, Joel [Wolf.Joel@epa.gov]; Wright, Tracy [Wright.Tracy@epa.gov]; Yowell, John [yowell.john@epa.gov]
Subject: News Articles (For EPA Distribution Only)

BNA DAILY ENVIRONMENT REPORT ARTICLES

First Move: House Tackles Energy, Environment Spending This Week

By Chuck McCutcheon

Posted June 17, 2019, 6:55 AM

It figures to be a busy week for energy and environment spending legislation.

Exxon Mobil Asks EPA to Examine Risks of Two Plastics Chemicals

By Pat Rizzuto

Posted June 14, 2019, 7:09 PM

Exxon Mobil Corp. has asked the EPA to evaluate the health and environmental risks of four chemicals used to make polyvinyl chloride, or PVC, flexible so it can be used for making car parts, carpet backing, coat wires and other purposes, the agency announced June 14.

INSIDEEPA.COM ARTICLES

Trump Executive Order Could End Host Of EPA Advisory Committees

Key EPA advisory committees governing air quality policy, children's health, environmental justice and environmental finance are among more than a dozen facing elimination after President Donald Trump issued an order requiring EPA and other agencies to disband one-third of their federal advisory committees (FACs) by Sept. 30.

GREENWIRE ARTICLES

Senators eye defense bill for PFAS compromise

Geof Koss, E&E News reporter

Published: Friday, June 14, 2019

Senate Environment and Public Works Chairman John Barrasso (R-Wyo.) and ranking member Tom Carper (D-Del.) are pushing bipartisan PFAS legislation as an amendment to the fiscal 2020 National Defense Authorization Act. C-SPAN

The top senators on the Environment and Public Works Committee have introduced an amendment to the National Defense Authorization Act that would require EPA to take a number of steps to regulate per- and polyfluoroalkyl substances (PFAS).

The amendment was submitted yesterday to the NDAA, S. 1790, by EPW Chairman John Barrasso (R-Wyo.), ranking member Tom Carper (D-Del.) and committee member Shelley Moore Capito (R-W.Va.). It includes compromise language requiring EPA to set a national primary drinking water regulation for the chemicals under the Safe Drinking Water Act within two years, according to a summary provided by the panel.

The amendment would also require EPA to request data from PFAS manufacturers under the Toxic Substances Control Act, while also tasking the agency with finalizing a 2015 rule governing "significant new uses" under the law (*Greenwire*, Oct. 23, 2018).

https://www.eenews.net/greenwire/2019/06/14/stories/1060581799

CHEMICAL WATCH ARTICLES

New York delays enforcing cleaning product disclosure until 2020

Second time the state has postponed enforcement

14 June 2019 / Cleaning products, Labelling, Legal cases, US states

New York state's Department of Environmental Conservation (NYSDEC) has announced a second pause in enforcement of its cleaning product disclosure programme, pushing the start-date back to 2 January 2020.

The Household Cleansing Product Information Disclosure Programme – which was finalised in June 2018 – will require large cleaning product manufacturers to post specific information about their products and the ingredients they contain on their websites.

This includes intentionally added ingredients other than fragrance ingredients and nonfunctional ingredients present above trace quantities.

The programme initially mandated manufacturers to post intentionally added ingredients online by 1 July. However, in January the NYSDEC announced that it would not begin enforcing violations of the July deadline until 2 October of this year.

The agency relayed the second three-month delay in enforcement via a 12 June update in the *Environmental Notice Bulletin*.

The programme has been subject to litigation by the Household & Commercial Products Association (HCPA) and the American Cleaning Institute (ACI), who say the agency has violated administrative procedure and have refused to work with affected stakeholders.

According to the ACI's Brian Sansoni, organisations are "awaiting further action by the court", and "do not know the timing of any decision-making by the court in New York or what that decision-making may entail."

The industry organisations member companies, however, are continuing to prepare for compliance with the regulation, despite the delay.

"We continue to support science-based ingredient transparency policies that provide meaningful information for consumers and workable implementation for manufacturers," said Mr Sansoni.

The programme also has a June 2020 compliance deadline for companies with fewer than 100 employees, and that remains unchanged.

In the meantime, the NYSDEC has encouraged manufacturers interested in creating a disclosure approach that meets the programme's requirements to contact the agency for a consultation.

At the time of publishing, the NYSDEC had not responded to Chemical Watch's question on why it has delayed enforcement for a second time.

Lisa Martine Jenkins

Americas reporter

Related Articles

- New York finalises cleaning products disclosure policy
- New York state delays enforcement of cleaning products disclosure
- ACI, HCPA sue New York over cleaning products disclosure policy

Further Information:

- NYSDEC notice
- Programme policies

Phthalate producers request TSCA risk evaluations for DIDP, DINP

ExxonMobil among companies seeking EPA review

14 June 2019 / Phthalates, TSCA, United States

The US EPA has announced the receipt of manufacturer requests to conduct risk evaluations under TSCA for two widely used phthalates: diisodecyl phthalate (DIDP) and diisononyl phthalate (DINP).

Both DIDP and DINP were identified in the 2014 update to the TSCA work plan. The substances are commonly used as plasticisers in the production of plastic and plastic coatings.

ExxonMobil Chemical Company asked for the DIDP evaluation, while a group including ExxonMobil Chemical Company, Evonik Corporation and Teknor Apex requested the one for DINP.

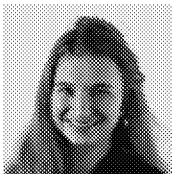
These companies are represented by the American Chemistry Council's High Phthalates Panel (ACC HPP), who said the move "will expedite transparent, fair, and evidence-based risk evaluations" of the substances.

The requests, received on 24 May, represent the third and fourth received by the agency since TSCA was amended in 2016. The first related to two fragrance ingredients with persistent, bioaccumlative and toxic (PBT) properties that had been flagged for expedited risk management action, but for which industry asked they be subject to evaluation first.

Under section 6(b)(4) of TSCA, the EPA issued a final rule that establishes the process for manufacturers to request an EPA-conducted risk evaluation of a chemical, under the conditions of use of interest to the manufacturer.

The EPA must notify the public within 15 days of a request's receipt. And within 60 days, the EPA will publish the receipt in the *Federal Register*, open a public docket for the request and provide at least 45 days for public comment. After the comment period closes, the agency has up to 60 days to either grant or deny the request.

Correction: This article was amended on 17 June to reflect that the EPA has previously received evaluation requests for two fragrances.



Lisa Martine Jenkins

Americas reporter

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- EPA names TSCA fast-tracked PBTs

Further Information:

- Manufacturer-requested evaluations
- TSCA final rule

P&G examines K-REACH challenges before pre-registration deadline

17 June 2019 / K-REACH, South Korea

South Korea's amended K-REACH is creating difficult and unique challenges for industry ahead of the 30 June pre-registration deadline.

Jeff Li, principal scientist at Procter & Gamble Technology (Beijing), raised a number of practical difficulties and questions concerning K-REACH during a recent AsiaHub Summit in Washington, DC including:

- pre-registration;

- polymer registration;
- animal testing and data requirements; and
- the translation of legislation.

Pre-registration

Pre-registration can be more complicated for consumer companies such as P&G because information is required for:

- substances in the product;
- raw materials including components of mixtures; and
- intentional breakdown products, such as from soaps.

For small companies, a spreadsheet might be enough, but P&G requires an IT system both to map substances and to track shipments so they can understand at any moment if a substance meets registration volume levels. Additionally, K-REACH, unlike EU-REACH, requires GHS classifications and P&G does not have this information for a "big portion" of substances, Dr Li said.

There are two options. The first is to go to suppliers or check databases to see what is available. Alternatively, a more practical approach may be to leave the substances as "not classified".

"Eventually," Dr Li said, "if it has to be registered, then GHS can be further classified."

Polymer registrations

While polymer registration is not new, K-REACH is the "first time there is the need to register a massive amount of polymers", Dr Li said, and polymers can make up a quarter of chemical inventories.

This is because while criteria for polymers of low concern (PLCs) are quite standard, the unique K-REACH requirement is to address those monomers that make up more than 2% of polymers.

This may mean "some very safe polymers" may not be classed as PLCs because of their monomers, as it is common for monomers to contain hazardous substances as they must react to form polymers. For example, he said, the very safe common polymer poly(ethylene oxide) is formed from the hazardous monomer ethylene oxide.

Usefully, Dr Li said, government listened to industry and changed the criteria. Previously, when a monomer was 2% of the ingredients of the polymer this was enough to trigger the requirement for the monomer's inclusion in the registration. Now the calculation of percentage has changed to how much of the monomer is left unreacted in residual amounts in the completed polymer. That said, still monomer residues, which are not actual polymer building blocks, can trigger registration.

Another big challenge for polymers unique to K-REACH, Dr Li said, is that companies must jointly register for the same polymer. The challenge is that even for the same Cas numbers, polymers vary significantly and so the same data often cannot be used. Polymers with the same Cas number can significantly vary in:

- molecular weight (MW);
- monomer reactants;
- residual products;

- end group reactors and chemical reactions; and
- shapes and tactility, for example in crystallinity, branching and cross-linking.

For example, Dr Li said, the substance Cas number 25322-53-8 comes in five forms including Carbowax PEG 4600, MW approx. 5,000 and polyox SWR coagulant, MW 5,000,000.

Government and industry understand that "this is a tough issue" and have responded. Dr Li said that the Korean Chamber of Commerce has created a polymer taskforce and there is draft guidance in circulation among a small group of organisations.

Animal testing and data requirements

Dr Li also sees challenges for animal testing used for registration data. While the legislation has the goal of minimising animal testing there are "practical challenges especially with National Institute of Environmental Research (Nier) evaluations".

His experience is that, even with very low volumes, animal testing may be required: "Typically there is a request for fish toxicity testing and acute inhalation testing in rats."

Changes to the legislation come after the humidifier disinfectant tragedy, in which humidifier steriliser products were linked to lung disease and deaths in South Korea. As a result, P&G first considers inhalation toxicity testing, Dr Li said. While there are other methods for establishing whether there is truly an inhalation risk, "so far we have made the argument but not been successful" in having these accepted.

The cost and timing of animal testing – perhaps $40-60,000 and months or years before the data is complete – means that for low volume chemicals P&G may reconsider and reformulate products: chemicals they believe have consumer benefits may not be launched in South Korea, he said.

In the long term, especially for cosmetics, there may be restrictions based on animal testing in other markets, he added. For example, a Nicnas decision prohibiting the use of animal test results in cosmetics registrations – even when a substance has multiple uses – may eventually become a restriction for launching cosmetics in Australia. On 14 February, Australia passed part of the Industrial Chemicals Bill 2017 that included a ban on animal testing for chemical introductions with an end use solely in cosmetics.

Further, animal testing results for components may result in re-classification and re-labelling, even if this is not a risk for the original product.

Scientific data

Most importantly, Dr Li said he wants South Korean to consider other scientific data for registration including:

- quasar;
- read across; and
- weight of evidence.

Dr Li said he is concerned over classification by hazard evaluation rather than risk considerations, which are uncertain. In P&G's experience, authorities "may" consider these based on the GHS classification.

For restricted substances, the legislation is better as it states they "shall" consider exposure. However, in reality, Dr Li said P&G don't know how this will be designated.

These issues are also a concern in K-BPR, he added, because of safety and labelling requirements for toxic or priority control substances irrespective of substance percentages. While "we just don't know what this re-labelling means to consumers", he said, eventually, given the number of toxic components, every consumer product will have a warning and so it loses importance.

Additionally, the blanket requirement for notification and communication to downstream users for controlled substances of more than 0.1% concentration and more than one tonne per year "does not truly aid safety". Dr Li said he understands the tragic background to the legislation, but rather than improving safety companies may well only be increasing their workload.

South Korea's government may be able to "learn from global practice" and ensure that designation lists more closely take risk into account, he added.

Translation of legislation

Finally, Dr Li, said more translations are required to help companies develop an "holistic" approach to the legislation. While South Korea has done a very good job in releasing regulations and guidance, the lack of translations has become a barrier to a broader understanding of the changes.

Sunny Lee

Asia editor

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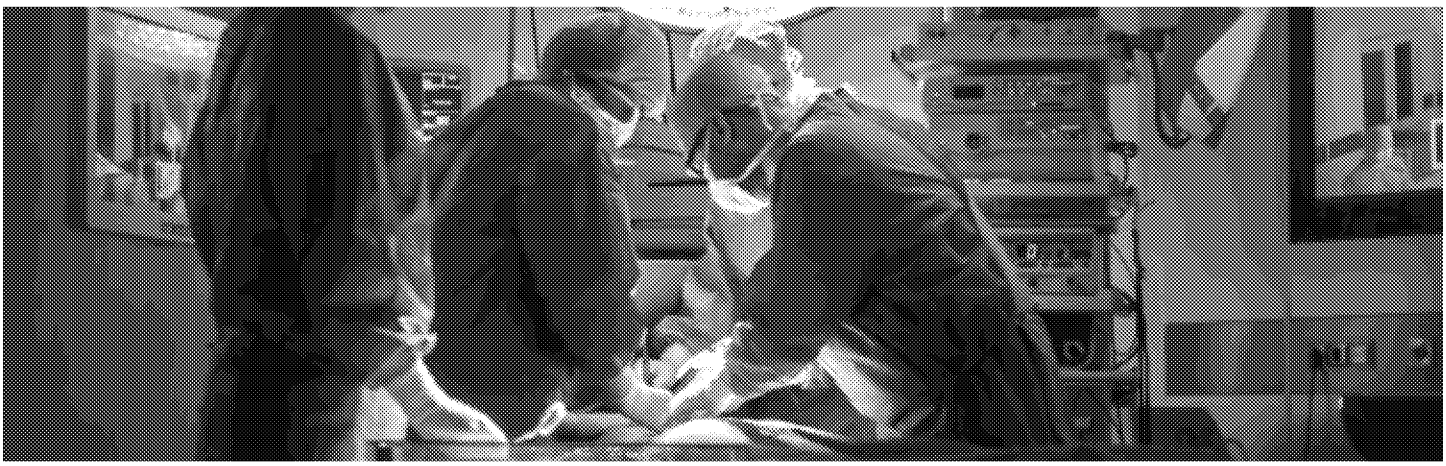
- P&G flags polymer and pre-registration rules as K-REACH challenges
- South Korea's draft implementation rules arrive for updated K-REACH
- US voices concern over South Korea's K-REACH implementation
- More detail on K-REACH enforcement rules as first deadline approaches
- K-REACH updated: lessons and challenges
- South Korea approves prioritisation of non-animal tests for K-REACH
- Reckitt Benckiser apologises for product linked to Korea deaths
- Australian NGOs celebrate 'huge win' on animal testing ban
- Restricted substances list (2017 revision)

- South Korea releases K-BPR implementation plans
- Major chemical company raises issues with South Korea's chemical tracking system

NGO Platform: Unnecessary EU exemption permits toxic chemicals in healthcare

17 June 2019 / Europe, Global, Healthcare, POPs

Dorota Napierska from Health Care Without Harm Europe, a European Registered Toxicologist with two PhDs in biochemistry and nanotoxicology, considers the impact of the EU's intervention at Stockholm Convention COP9.



With a worrying disregard of accepted UN protocol, the EU has successfully requested a five-year global exemption to continue using perfluorooctanoic acid (PFOA) in medical textiles.

Despite the wide availability of existing alternatives to this extremely persistent, bioaccumulative and toxic chemical, an EU delegation made the request during the Stockholm Convention's COP9 where parties had agreed to a worldwide ban of PFOA.

Back in June 2015, the EU delegation had actually nominated PFOA, its salts, and related compounds, to be listed under the Stockholm Convention and participated throughout the process that culminated in the global PFOA ban last month. An exemption for medical textiles was already deemed unjustified during the evaluation process by the international group of UN experts.

'The EU has not only displayed a disturbing failure to protect EU citizens from the hazards of PFOA, but also shown a flagrant disregard and disrespect for UN's careful review process and the international protocol'

By requesting a last-minute additional exemption for medical textiles, the EU has not only displayed a disturbing failure to protect EU citizens from the hazards of PFOA, but also shown a flagrant disregard and disrespect for UN's careful review process and the international protocol for listing exemptions under the Stockholm Convention.

Exemptions are a serious matter – how governments choose to address the use of toxic chemicals such as PFOA and citizens' exposure to them is a stark reminder of their ambition to uphold our human right to a non-toxic environment.

PFOA

PFOA is only one substance in the large class of fluorinated chemicals known as PFASs, which are emerging pollutants of the 21st century. Due to its technical properties (repellent to water, oil, and grease/stains) PFOA is used in such varied

products as clothing, furniture, adhesives, food packaging, heat-resistant non-stick cooking surfaces, and the insulation of electrical wire. Due to the surfactant properties of both PFOA and its related non-polymeric surfactants, these substances are also used as firefighting foams, wetting agents, and cleaners.

These many and varied applications lead to releases of PFOA and related substances into the environment worldwide consequently contaminating groundwater, drinking water, wildlife, and people. PFOA-related emissions have even been found in remote areas such as the Arctic – PFOA is a transboundary pollution problem. PFOA, also known as "forever chemical", is a persistent man-made chemical and does not undergo abiotic or biotic degradation in the environment. Evidence from contaminated sites shows that it is very difficult to reduce the level of pollution once it has occurred.

Exposure to PFOA typically takes place during consumption of contaminated drinking water and food (including breast feeding), inhalation of contaminated indoor air and dust, or from consumer products containing PFOA, its salts and related compounds. Biomonitoring studies have detected PFOA and related compounds in blood samples of almost all individuals checked.

Whilst PFOA is quickly absorbed, it is not metabolised and is distributed throughout the body where it can be transferred to foetuses through the placenta. A considerable number of adverse health effects have been linked with PFOA exposure in humans: increased cholesterol levels, ulcerative colitis, thyroid disease, cancers, pregnancy-induced hypertension, and reduced birth weight.

'These chemicals are much more damaging to human health than previously thought'

The European Food Safety Agency (Efsa) recently set the provisional tolerable weekly intakes for PFOA at six nanograms per kilogram of body weight, lowering it from 1,500ng daily – an extreme reduction of 99.99% and a clear acknowledgement that these chemicals are much more damaging to human health than previously thought.

Efsa has also expressed concern that a large portion of the EU population already exceeds these new safety levels. To limit the risk of ubiquitous and long-term exposure of humans and the environment, a phase-out of these substances is the only effective measure and any unjustified source of PFOA should be avoided.

PFOA in medical textiles

The term 'medical textiles' covers an almost limitless range of applications in healthcare from bandages or pressure garments to implanted products such as sutures and fabrics for orthopaedic devices, etc.

Membranes used in certain medical textiles (eg, in surgical gowns) could consist of PTFE (polytetrafluoroethylene) fluoropolymer that function as a repellent, providing protection from blood and body fluids to reduce the risk of cross-infections for both patients and staff.

PFOA can be used as production aid in the manufacture of PTFE. Leading global fluoropolymer manufacturers and progressive companies, however, are now using alternative substances such as fluorinated polyether carboxylates. The evaluation of PFOA by UN experts identified several potential alternatives for use in textiles such as short-chain fluorinated alternatives, non-fluorine containing alternatives, and non-chemical alternatives, including those that meet regulatory requirements and are in current use.

No specific application has been identified during the Stockholm Convention evaluation process that absolutely requires PFOA chemistry ie, there are no applications of PFOA in medical textiles where alternatives do not already exist. Based on the evaluation of available information a specific exemption for use in membranes intended for use in medical textiles was therefore not recommended.

How does PFOA enter the environment?

Releases of PFOA and related compounds into the environment occur throughout products' life cycles (during the manufacture, use, and disposal of articles and products treated or contaminated with PFOA). During manufacture, PFOA can be directly released in the production of the raw substances (including PFOA as an impurity in the manufacturing of PFOA-related compounds).

There are also significant concerns surrounding releases of PFOA and by-products from textiles during use (cleaning, washing, sterilisation) as well disposal. The environmental and health impacts of PFOA disposal (particularly incineration) still require further research. In developing and transition countries there is greater prevalence of open combustion and other uncontrolled combustion processes, and these should also be considered as a significant source of global PFOA release.

In 2018, the global medical textiles market was valued at more than US$16bn (£12.7bn) and is projected to grow annually by 4.9% by 2025 with countries such as the UK, France, Italy and Germany dominating the European market.

Textiles in general have been recognised as a major emission source of PFOA and PFOA-related substances by the EU Risk Assessment Committee (Rac), who also observe that the volume of PFOA and related substances used in textiles still seems to be high. It is difficult to assess which medical textiles contribute the most to PFOA pollution of the environment, as detailed information about the number of applications and volumes used is limited.

During the EU public consultation industry stakeholders indicated that the European textile industry has already limited PFOA-related emissions to approximately 5-10kg per year. They did not, however, clarify the applications and amount of PFOA actually used in medical textiles, and the Committee for Socio-Economic Analysis (Seac), expressed concerns that the textiles sector appears to have little reliable information on levels of PFOA-related substances in finished products.

Furthermore, and perhaps more worrying, there appears to be even less information on PFOA in textile products made outside Europe. Considering the significant projected growth of the global medical textiles market, we can expect higher annual volumes of PFOA and related substances released to the environment.

Why did the EU ask for this exemption?

During COP9, the EU delegation reasoned that an exemption for using PFOA in manufacturing of PTFE for medical textiles membranes was required "because such exemptions already exist in EU legislation".

'The EU has effectively lowered the bar in global chemicals management and brought other countries in line with its own weak regulation'

In a dismissal of both UN expert opinion and industry stakeholders acknowledging safer alternatives – the EU has effectively lowered the bar in global chemicals management and brought other countries in line with its own weak regulation.

Civil society had already expressed concerns about the proposed EU PFOA regulation back in 2016 raising issues such as unjustified derogations and conflicts of interest. Following public consultations, both Rac and Seac adopted a large number of industry-submitted derogations in their official opinions – including exemption for medical textiles. The committees have provided no justification about the environmental and health impacts of these important additions to their draft opinions, and appeared to be merely rubber-stamping industry proposals.

Perhaps the most worrying aspect is that no information on the scope of applications for medical textiles, the volume of PFOA used in medical textiles, or non-availability of alternatives to PFOA was provided to the UN POPRC experts during the evaluation process that could justify an exemption under the Stockholm Convention.

Healthcare can lead the way

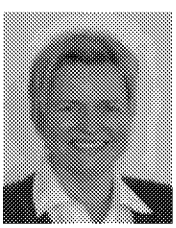
This marks yet another unnecessary exemption that permits continued use of PFOA in healthcare, even when a robust market exists for PFOA-free healthcare products. Greenhealth Exchange, a cooperative with $4bn in annual purchasing for more than 100 hospitals in the US did not support the grounds for the exemption and also highlighted the special responsibility of the healthcare industry to set a positive example.

Extremely persistent, very toxic, and abundant in the environment, PFOA can be considered one of the world's most dangerous chemicals and difficult to address. We must avoid any exemptions undermining the Stockholm Convention protective provisions.

Human health is intrinsically linked to our environment, and the healthcare sector must strongly advocate for reduced environmental impacts from human activity – including from the healthcare sector itself. With its unique healing mission, healthcare must lead by example.

The EU has undermined progress towards a true global ban of PFOA, and deferred its responsibility to address PFOA in medical textiles until 2025 – however, during that time it is the healthcare sector that not only must treat those made ill by PFOA, but also go beyond the failings of our policy-makers to protect our health and environment.

Through strategic and sustainable procurement, the healthcare sector can fulfil its healing mission and surpass the restrained and unambitious policies of the EU to demonstrate that substituting PFOA with safer alternatives is both feasible and viable – a sentiment even expressed by representatives of the fluorochemicals industry present at COP9.



Dr Dorota Napierska

View transparency statement

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- Feature: Is the EU lowering global standards for toxic and persistent substances?

- NGOs criticise EU for requiring exemption from global PFOA ban
- Efsa panel lowers tolerable intakes for PFOS and PFOA
- ICCA calls for 'modernisation' of UN POPs Convention

Further Information:

- Stockholm Convetion COP9
- OECD Environment Directorate
- PFOA — main concerns and regulatory developments in Europe
- Forever chemical explanation
- Efsa: Provisional tolerable weekly intakes for PFOA
- Efsa scientific opinion
- Stockholm Convention, addenda to reports
- Medical textiles market report
- EU public consultation
- Echa: Registry of restriction intentions

Guest Column: Myths around sharing of EHS information on chemicals

17 June 2019 / Data, GHS, United States

Dr Gregory G Bond of Manitou View Consulting, who spent 35 years working for Dow, assisted the UN in researching and writing its report on chemical management and information sharing. He reflects on the report's findings.

A report by UN Environment and the International Council of Chemical Associations (ICCA), *Knowledge management and information sharing for the sound management of industrial chemicals*, goes a long way toward dispelling some common myths about the availability of environmental, health and safety (EHS) information on industrial chemicals in commerce.

Mainstream and social media often claim that there are more than 100,000 chemicals in commerce – some published estimates reach as high as more than 140,000 – and yet little is known about their potential health impacts.

'The true story is more complex, far less dramatic, and should provide consumers with greater reassurance'

Such rhetoric is scaring the public and further eroding their trust that government and industry are doing enough to protect them from harm. However, the true story is more complex, far less dramatic, and should provide consumers with greater reassurance.

UN Environment and ICCA share a number of important perspectives, objectives and goals. For instance, they both agree that while chemistry provides important benefits to society and is critical to solving some of humanity's greatest challenges, it must be practiced responsibly.

Working together with a host of others and for nearly two decades, they have partnered on the Strategic Approach to International Chemicals Management (Saicm) whose aim is to achieve sound management of chemicals throughout their life cycle so that by the year 2020, chemicals are produced and used in ways that minimise significant adverse impacts on the environment and human health.

Knowledge and information sharing are critical components of the Saicm goal. UN Environment and ICCA undertook their research and analysis to provide stakeholders with guidance on where to find chemical EHS information and how to use it.

Their report provides a comprehensive inventory of the available public databases of EHS information and a descriptive evaluation of their quality as measured by five criteria:

- scope of chemicals addressed;
- ease of access and use;
- breadth and depth of EHS information available;
- quality of the underlying information; and
- procedures to keep the information current.

The major findings of the report can be summarised as follows.

- Using the most recent data available from the EU, US, Canada, Japan and China, and making best and worst case assumptions, there are an estimated 40,000 to 60,000 industrial chemicals in commerce globally, far fewer than is commonly claimed.
- Furthermore, approximately 6,000 of those account for more than 99% of the total volume of industrial chemicals in commerce globally.
- A number of factors contribute to the uncertainty in the estimates of the numbers of chemicals, including: i) a lack of chemical inventories for many countries in the world; ii) uncertain and variable definitions of industrial chemicals in commerce (ie, different scopes); iii) varying volume thresholds for reporting; iv) uncertainty as to whether or not listed chemicals are actually on the market; and v) and lack of reporting or misreporting to government authorities.
- Contrary to many claims, there exists EHS information to support varying degrees of screening level hazard and risk assessment for the majority of the highest production volume chemicals.

- The report identifies more than 100 publicly available EHS information sources and provides detailed profiles of 41 of the largest and most comprehensive of them: i) seven act as data portals which provide information seekers with easy access to multiple, third-party owned databases. A good example is OECD's eChemPortal, which is an excellent starting point for those who wish to know where to find EHS information globally available on a chemical of interest; ii) 10 provide access to EHS-type regulatory decisions, but not to any specific EHS data *per se.* Perhaps foremost among them is Canada's Categorization Results database as it represents an effort to characterise the hazards and make regulatory decisions of all 23,000 chemicals in commerce there; iii) The remaining 24 represent primary EHS information sources.

Of the remaining 24 representing primary EHS information sources:

- Seven of them are managed by inter-governmental organisations, 14 by regional or national governments and three by NGO's.
- The largest and most comprehensive databases were launched after Saicm was adopted in 2006 demonstrating the important role Saicm has played in sharing knowledge and information among stakeholders.
- Echa's CHEM is the largest and most comprehensive of them with hazard, use, exposure, risk and risk management information for the 22,000 plus chemicals produced or imported into the EU
- The majority of sources include EHS information on a broader group of chemicals found in the environment, regardless of whether they remain in commerce.
- Several (eg, Environmental Working Group's Skin-DeepTM, GoodGuide) are designed to assist those who are looking to substitute less hazardous chemicals for more hazardous ones and four of them increase transparency of the identity and hazard characteristics of chemicals used in specific categories of consumer products.

Strengths of the report include its narrow focus on industrial chemicals because of recent increased public concern; the comprehensiveness of the inventory of publicly accessible EHS databases assembled (ie, breadth of geographic coverage, and type of EHS information); the objective assessment of the quality of those databases, and the reports' orientation toward helping information seekers navigate the complex data landscape to optimise their efforts.

The report and the databases themselves are not without their limitations and they have been identified and thoroughly discussed in the report. Chief among them is that gaps in EHS knowledge for lower production volume chemicals persist, and Confidential Business Information (CBI) claims for some chemicals can limit the information available to the general public. A lack of information on uses and exposures to chemicals in developing countries is especially challenging.

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Nevertheless, there are several reasons to be optimistic that going forward information gaps can be closed at an accelerated rate. The combined effect of recently adopted legislation in multiple regions and countries (eg, the EU, US, South Korea and China) that requires manufacturers and importers to collect and publicly report hazard, use, exposure and risk information on their chemicals; the increasing focus on safe substitution and greener chemistry; as well as the advent and acceptance of new tools and methods (eg, read across, computational toxicology) provide excellent opportunities to close such information gaps more rapidly than in the past.

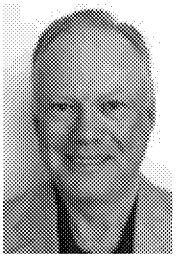
The report should prove helpful to authorities, especially in developing countries, in several important ways:

- Giving ready access to EHS information on a wide range of industrial chemicals in commerce for use in implementation of the UN Globally Harmonized System (GHS) of classifying and labelling chemicals.

- Facilitating the development of strategies for gathering local use and exposure information critical for conducting risk assessments and prioritising chemicals for further risk management.
- Providing easy access to the most comprehensive EHS information that is available on chemicals of interest allowing identification of missing data for prioritised action to fulfil them.
- Assisting their discussions on specific chemicals and chemical classes identified as concerns to Saicm (eg, brominated flame retardants, perfluorinated chemicals, and others).

Finally, citing the report's findings, ICCA recently called for national bodies and institutions in the countries with the most advanced chemicals legislation to take the lead in developing an "international navigator" – a global repository of publicly available information on chemicals – which could be based on the publicly available information in existing databases identified in the report. Creating a global data repository would significantly contribute to the capacity building efforts in those countries which have just started developing legislation on chemical safety and have limited knowledge on chemicals and their effects.

The views expressed are those of the expert author and are not necessarily shared by Chemical Watch.



Dr Gregory G. Bond

View transparency statement

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- OECD says its chemical work saves €300m annually
- Expert Focus: Using chemical substance data for global compliance
- Two databases added to OECD's eChemPortal
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- US retailer releases details of its sustainable product standard
- Study highlights potential hazards of nine alternative flame retardants

Further Information:

- Knowledge management and information sharing for the sound management of industrial chemicals
- UN Environment
- ICCA

- Saicm report
- Saicm goals
- OECD eChemPortal
- Canada's Categorization Results
- Echa's CHEM
- Chemical industry call for global data sharing
- Saicm submission

Italy creates group promoting alternative methods to animal testing

17 June 2019 / Alternative approaches to testing, Cosmetic products Regulation, Personal care, REACH

The Italian health ministry has set up a working group to promote alternative methods to animal testing for scientific purposes.

It will be composed of institution representatives and experts on alternative methods in bioethics and animal experimentation.

Other stakeholders, including scientific research associations with national relevance, can also request to be part of the group.

The working group will be tasked with:

- checking that EU law is properly implemented;
- making sure scientific information on animal wellbeing and alternative research methods are correctly used and funded; and
- promoting initiatives to ensure accurate information and transparency are delivered, in particular regarding animals used, their treatment conditions, aims of research and results obtained.

The working group will meet every month and present a report to the minister every six months.

"Monitoring experiments on the use of animals is an ethical but also a scientific achievement," health minister Giulia Grillo said.

A balance between research and science and "the need to go beyond traditional methods to minimise the number of animals used" is needed, she added.

The decision is in line with an Italian legislative decree implementing the EU Directive on the protection of animals used for scientific tests, published in 2010.

Since then, the EU has taken further steps by implementing a ban on the sale of cosmetics tested on animals in 2013.

In 2015, the Commission rejected a petition signed by more than one million EU citizens, urging it to put forward legislation to ban all experiments on animals.

In February 2018, MEPs from the European Parliament's environment committee approved a resolution, aiming to establish a global ban on animal testing for cosmetics by 2023.

Related Articles

- EU implements ban on sale of cosmetics tested on animals
- EU Commission rejects citizen initiative on animal testing
- MEPs back push for global ban on cosmetics animal testing

Further Information:

- Health ministry press release (in Italian)
- Ministerial decree (in Italian)
- Call for interest (in Italian)

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